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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,618	04/20/2004	Robert E. Dudley	04274661	7286

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EXAMINER	
JEAN-LOUIS, SAMIRA JM	
ART UNIT	PAPER NUMBER
1627	

NOTIFICATION DATE	DELIVERY MODE
11/30/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@mayerbrown.com

Office Action Summary	Application No.	Applicant(s)	
	10/829,618	DUDLEY ET AL.	
	Examiner	Art Unit	
	SAMIRA JEAN-LOUIS	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08/05/09*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6-9,11-15,17,18,22-28 and 43-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6,7,9,22,43-45,47,48 and 50-53* is/are rejected.

7)☒ Claim(s) *8, 11-15, 17-18, 23-28, 46, and 49* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

This Office Action is in response to the amendment submitted on 08/05/09. Claims 1, 6-9, 11-15, 17-18, 22-28, and 43-53 are currently pending in the application, with claims 2-5, 10, 16, 19-21, and 29-42 having being cancelled. Accordingly, claims 1, 6-9, 11-15, 17-18, 22-28, and 43-53 are being examined on the merits herein.

Receipt of the aforementioned amended claims is acknowledged and has been entered.

Applicant's argument with respect to the rejection of claim 8 under 35 U.S.C. § 112, second paragraph has been fully considered. Given that applicant has amended claim 8, such rejection is now moot. Consequently, the rejection of claim 8 under 35 U.S.C. § 112, second paragraph is hereby withdrawn.

Applicant's arguments against the rejection of claims 1, 6-9, 11-18, and 22-28 under 35 U.S.C. § 103(a) has been fully considered. Given that Applicant stated on the record that Dudley (U.S. 2003/0022877) is unavailable as prior art since the instant invention possesses an earlier priority date, such rejection is now moot. Consequently, the rejection of claims 1, 6-9, 11-18, and 22-28 under 35 U.S.C. 103(a) is hereby withdrawn.

For the foregoing reasons, the rejections of record are withdrawn. The following Obviousness Double Patenting (ODP) rejections are being made.

Provisional Non-Statutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 6-7, 9, and 22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27-30, 39-45, and 47-48 of copending Application No. 10/531,526 (hereinafter Dudley US Patent Application No. '526). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to overlapping method of treatment comprising administering a hydroalcoholic gel containing an effective amount of testosterone, a penetration enhancer, a C1-C4 alcohol, and gelling agent. The claimed invention and co-pending application Dudley '526 are rendered obvious over another as the claimed invention teaches a method of treating or reducing the risk of a depressive disorder wherein administration of the hydroalcoholic gel resulted in a serum testosterone is maintained between about 400 ng testosterone per dL to about 1050 ng testosterone per dL whereas Dudley '526 teaches a method of improving sexual performance comprising administering the same hydroalcoholic gel along with a pharmaceutical agent for erectile dysfunction. While the instant invention is directed to a method of treating a depressive disorder, applicant's specification described sexual performance difficulty as a type of depressive disorder (i.e. decreased libido). Moreover, because patients with erectile dysfunction may

necessarily be depressed, the Examiner maintains that the instant invention and co-pending application overlap in scope. Additionally, given that treatment of erectile dysfunction can include additional pharmacological agents for erectile dysfunction and in light of the comprising language in the instant claims, the Examiner contends that such pharmacological agents are encompassed in the instant invention. As for the serum testosterone concentration recited in the instant claims, the Examiner maintains that such serum testosterone concentration is a necessary property of the hydroalcoholic gel that is also claimed by the co-pending application. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No. 10/531,526.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 6-7, 9, and 22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27-30, 39-45, and 47-48 of copending Application No. 10/867,435 (hereinafter Dudley US Patent Application No. '435). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to overlapping methods of treatment comprising administering a hydroalcoholic gel containing an effective amount of testosterone, a penetration enhancer, a C1-C4

alcohol, and gelling agent. The claimed invention and co-pending application Dudley '435 are rendered obvious over another as the claimed invention teaches a method of treating or reducing the risk of a depressive disorder wherein administration of the hydroalcoholic gel resulted in a serum testosterone is maintained between about 400 ng testosterone per dL to about 1050 ng testosterone per dL whereas Dudley '526 teaches a method of improving sexual performance comprising administering the same hydroalcoholic gel along with a pharmaceutical agent for erectile dysfunction. While the instant invention is directed to a method of treating a depressive disorder, applicant's specification described sexual performance difficulty as a type of depressive disorder (i.e. decreased libido). As a result, a method of treating a depressive disorder is also interpreted as a method of improving sexual performance. Moreover, because patients with erectile dysfunction (i.e. sexual performance difficulty) may necessarily be depressed, the Examiner maintains that the instant invention and co-pending application overlap in scope. Additionally, given that treatment of erectile dysfunction can include additional pharmacological agents for erectile dysfunction and in light of the comprising language in the instant claims, the Examiner contends that such pharmacological agents are encompassed in the instant invention. As for the serum testosterone concentration recited in the instant claims, the Examiner maintains that such serum testosterone concentration is a necessary property of the hydroalcoholic gel that is also claimed by the co-pending application. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove

and are prima facie obvious over the cited claims of corresponding application No. 10/867,435.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 43-45, 47-48, and 50-53 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 33, 39-41, 44, 57, 68, 70-72, and 74-75 of copending Application No. 10/867,445 (hereinafter Dudley US Patent Application No. '445). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to overlapping methods of treatment comprising administering a hydroalcoholic gel containing an effective amount of testosterone, a penetration enhancer, a C1-C4 alcohol, and gelling agent. The claimed invention and co-pending application Dudley '445 are rendered obvious over another as the claimed invention teaches a method of treating or reducing the risk of a depressive disorder comprising administration of a hydroalcoholic gel whereas Dudley '445 teaches a method of treating hypogonadism (i.e. low testosterone) comprising administering the same hydroalcoholic gel. While the instant invention is directed to a method of treating hypogonadism and the co-pending application is directed to a method of transdermally delivering testosterone to a male subject in need thereof, the Examiner contends that hypogonadism is characterized by low testosterone and thus such subjects would

necessarily be in need thereof. Thus, the aforementioned claims of the instant application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No. 10/867,445.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Objections

Claims 8, 11-15, 17-18, 23-28, 46, and 49 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L. /

Examiner, Art Unit 1617

11/20/2009

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627